

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AMGEN INC. and AMGEN )  
MANUFACTURING LIMITED, )  
                          )  
Plaintiffs,             )  
                          )  
                          )  
v.                       ) C.A. No. 18-1064-CFC  
                          )  
HOSPIRA, INC. and PFIZER INC., ) **PUBLIC REDACTED VERSION**  
                          )  
Defendants.             )  
                          )  
                          )

**PLAINTIFFS' RESPONSIVE LETTER BRIEF IN OPPOSITION TO  
DEFENDANTS' MOTION TO STRIKE**

**Dated: December 4, 2019**

Dear Judge Connolly:

Plaintiffs (“Amgen”) respectfully submit this response to Defendants’ (“Pfizer’s”) motion and proposed order to strike portions of Amgen’s infringement contentions and expert report. The parties dispute whether Amgen has proposed a new construction for a claim term never construed by this Court—“applying the refold solution to a separation matrix”—but which the parties agreed means “applying the refold solution to a separation matrix without intervening steps of dilution, centrifugation, dialysis, or precipitation.” D.I. 64, D.I. 55. Amgen’s infringement contentions and expert reports do not, as Pfizer alleges, assert a new infringement theory or propose a new claim construction. Rather, Amgen’s infringement contentions and expert reports *apply* the agreed-upon construction to show infringement by Pfizer’s accused process—for example by citing to additional evidence from fact discovery, such as the testimony of Pfizer’s corporate witness Goran Valinger. Ex. 1, Sup. Appx. A. This is entirely proper. Even Pfizer itself anticipated that the meaning of the technical terms in the parties’ agreed-upon construction would be addressed “through expert discovery.” Ex. 2 at 4. Nevertheless, Pfizer now asserts that Amgen has proposed “an entirely different claim construction” for the term. *Id.* at 2, 4. Pfizer is incorrect.

*First*, Pfizer says that there is a new claim construction because Amgen’s expert “tethers the meaning” of dilution, dialysis, centrifugation, and precipitation to Wang and Oliner (D.I. 102, Letter Br. at 1-2), and he opines [REDACTED]

[REDACTED] Letter Br. at 2. Pfizer misunderstands Amgen’s expert. Amgen’s expert explains how Pfizer’s process practices the agreed-upon construction of the claim limitation as a person of ordinary skill in the art would understand the technical steps recited in that construction. Ex. 3 at ¶¶ 39-71. He did not opine that the claim term excludes only the processes of Wang and Oliner, but rather that those references provide “excellent examples” of steps excluded from the claim scope, to explain how a person of ordinary skill would understand this technology, and more specifically those steps. For example:

With respect to a POSITA’s understanding of “dilution” in the agreed-up[on] construction, *Wang et al. is an excellent example* of an approach that requires a dilution step. It discloses dilutions of more than 25-fold in the context of binding between immunoglobulin (IgG) and Protein A resin in the presence of 0.18 M guanidinium chloride (GdmCl), which is a denaturant used to solubilize IgG and is normally used at concentrations of 5 M or higher. With respect to a POSITA’s understanding of “dialysis” in the agreed-upon construction, *Oliner is an excellent example* of an approach that uses dialysis. It discloses that “The refolded protein was dialyzed against 1.5 M urea, 50mM NaCL, 50 mM Tris, pH 9.0.” With respect to a POSITA’s understanding of “centrifugation” and “precipitation” in the agreed-up construction, *Oliner is an excellent example* of an approach that uses centrifugation to remove a large magnitude of precipitate. It discloses that the “precipitate was removed by centrifugation, and the supernatant was

adjusted to a pH of from 5 to 6.5, depending on the isoelectric point of each fusion product.” The approach disclosed in Oliner (which the invention seeks to avoid) stands in contrast to other prior art approaches in which some material is removed by microfiltration through 0.1 or 0.2 micron filters.

*Id.* at ¶ 41 (emphases added) (citations omitted).

It is proper for Amgen to provide its understanding of the terms “dilution, centrifugation, dialysis, or precipitation” in its infringement analysis. Parties are entitled to, and expected to, “clarify and defend” the “original scope of [the parties’] claim construction.” *See Cordis Corp. v. Boston Sci. Corp.*, 658 F.3d 1347, 1356 (Fed. Cir. 2011). How one of ordinary skill understands the claim term as construed is not a new construction; rather, it is a part of the infringement analysis. *See Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1358-59 (Fed. Cir. 2012). Here, one of ordinary skill in the art applying the claims to the accused process would look to the Wang and Oliner prior art to understand what the steps of “dilution, centrifugation, dialysis, or precipitation” are in this field. Those steps are technical in nature and have a meaning to those of skill in the relevant art that can be context dependent. Thus, contrary to Pfizer’s argument, Amgen is not “attempt[ing] to narrow the scope of the disclaimed steps.” Letter Br. at 2-3. Indeed, as the Court recognized during the *Markman* hearing, how the facts apply to the construction “would be an infringement issue” and the Court would expect expert testimony on it. *See* D.I. 64 at 38:10–41:20 (for “an infringement issue,” the parties should bring “two experts . . . and the jury decides”). To be clear, Amgen does not assert, as Pfizer argues, that Wang and Oliner are the only examples that could aid the jury to understand the claimed invention. Letter Br. at 1-2. But they are cited in the patent and thus it is eminently reasonable to use them as examples.

Pfizer incorrectly argues that Amgen’s application of the claim term, as it would be understood by a person of ordinary skill, to the accused process in an infringement analysis is not permitted. The parties’ infringement dispute for this term is one of fact involving application of the claim term to the accused process. Even assuming *arguendo* that Amgen’s contentions raise a new claim construction issue (which they do not), then at most the parties have a disagreement regarding the meaning of this claim term that has not been considered or resolved by the Court. Even Pfizer acknowledges that it is trying to raise a legal issue: the “scope of a surrender of subject matter during prosecution.” Letter Br. at 2-3. Should the Court take up this issue, Amgen’s reference to the prior art as informing the application of the claim term to the accused process is consistent with the intrinsic evidence. Both Wang and Oliner are cited on the face of the patent. Wang is also cited in the specification of the ’997 Patent concerning “dilut[ion].” *See, e.g.*, D.I. 1-1, col. 1:41-55, 4:52-57, 15:50-66. Moreover, during prosecution, Amgen distinguished Oliner from the ’997 Patent. Ex. 4 at 11, 12.

**Second**, Pfizer’s asserted surprise as to Amgen’s infringement contentions and opening expert reports ignores the parties’ past correspondence and filings.

Letter Br. at 3; Ex. 2 at 3. Amgen's claim construction proposal cited to: (1) the specification of the '997 Patent at column 4, lines 52-57 which cites Wang; (2) the prosecution history of the '997 Patent and its parent, the '878 Patent, including where Amgen distinguished Oliner on the basis of Oliner's dialysis, precipitation, and centrifugation; and (3) Oliner, including the portion of Oliner discussing dialysis, precipitation, and centrifugation. *See* Ex. 5 at 2. Pfizer's proposal cited to much the same evidence. *See* Ex. 6 at 1. Further, Pfizer argued during claim construction that this Court should apply the construction given to this term by the district court in *Amgen Inc. v. Mylan Inc.*, which held that the meaning of the claim term "applying the refold solution to a separation matrix" is also informed by much of the same evidence including Oliner. *See* Ex. 7; *Amgen Inc. v. Mylan Inc.*, No. 2:17-cv-01235, 2018 WL 6061213, \*13-14 (W.D. Pa. Nov. 20, 2018).

Amgen took Pfizer's arguments and the parties' exchanges at face-value. It was not until Pfizer's October 29, 2019 letter that Amgen learned that Pfizer now disagrees that the agreed-upon construction for the "applying" term is informed by the intrinsic evidence. Ex. 2 at 2-4. Pfizer is apparently taking this position now even though it understood throughout fact discovery that these prior art references provided context to understand the claimed invention, as evinced by Pfizer's questions to Amgen fact witnesses and the deposition testimony of those witnesses. *See, e.g.*, Ex. 8 at 37:5–54:14, 105:20–108:19; Ex. 9 at 292:5–293:21, 297:8-15, 303:19-304:6. For example, Pfizer asked Amgen's patent prosecutor multiple questions about Oliner and the dialysis, centrifugation, and precipitation performed in Oliner. Ex. 8 at 37:10–54:14, 105:20–108:19. Roger Hart, an inventor of the '997 Patent, testified about Wang during his deposition including dilution. Ex. 9 at 292:5–293:21, 297:12-16, 303:19-304:6. This refutes Pfizer's argument that Amgen's witnesses [REDACTED]

[REDACTED] Letter Br. at 3.

**Third**, Pfizer incorrectly argues prejudice. Letter Br. at 3. Pfizer sought and received testimony on Oliner and Wang, the facts relating to Pfizer's manufacturing process are uniquely within its own control, and Pfizer's experts have already addressed Amgen's alleged new construction in their invalidity expert reports. *See, e.g.*, Ex. 8 at 37:10–54:14, 105:20–108:19; Ex. 9 at 292:5–293:21, 297:8-15; Ex. 10 at ¶¶ 118, 125-127, 134-137; Ex. 11 at ¶¶ 185-186, 193-195, 202-205. Moreover, Pfizer will be able to have its experts address Amgen's infringement contentions in its upcoming non-infringement reports and seek expert discovery from Amgen's experts under the existing case schedule; thus, Pfizer cannot be heard to allege prejudice. And given that Pfizer considers the parties' agreed-upon construction to be its "plain and ordinary meaning," as Pfizer's counsel stated in a November 5 teleconference, the parties should go on to present evidence at trial as to their dispute over what the plain and ordinary meaning is. Pfizer appears to recognize this lack of prejudice given its cursory treatment of prejudice and failure to address the other *Pennypack* factors. Letter Br. at 3.

Respectfully,

*/s/ Robert W. Whetzel*

Robert W. Whetzel (#2288)

Cc: Counsel of Record (via CM/ECF & E-Mail)

Attachments